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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,448	11/21/2003	Fred H. Burbank	R0367-01003	3039
7590 05/13/2005			EXAMINER	
Edward J. Lynch DUANE MORRIS LLP One Market Spear Tower, Ste. 2000 San Francisco, CA 94105			JEFFERY, JOHN A	
			ART UNIT	PAPER NUMBER
			3742	
DATE MAILED: 05/13/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,448

Applicant(s)

BURBANK ET AL.

Examiner

John A. Jeffery

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-60 is/are allowed.
- 6) ☒ Claim(s) 61-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20050418.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer Approved

The terminal disclaimer filed 1/10/05, disclaiming the terminal part of any patent granted on the instant application which would extend beyond the expiration date of U.S. Patent 6,347,241 and copending application 10/684,124, has been approved and entered.

New Matter

The amendment filed 2/1/05 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- The limitation calling for the bioresorbable body to swell "to substantially fill the biopsy site" (claims 65 and 74);
- All limitations calling for "relocating" the biopsy site (claims 69, 75, and 76); and
- the limitation calling for the bioresorbable body being a polymer formed of a polylactic acid (claim 72)

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65, 69, 72, and 74-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For the reasons set forth above, applicant has added new matter to claims 65, 69, and 74-76. Therefore, those claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 63 and 66-76 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. The test for definiteness under 35 U.S.C. § 112, second paragraph is whether “those skilled in the art would understand what is claimed when the claim is read in light of the

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specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).

Claims 63 and 66: The claims are incomplete because there is no period at the end of either claim. Consequently, it is unclear whether applicant intended to recite additional limitations – even when read in light of the specification.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 61-76 are rejected under 35 USC 102(e) as being anticipated by Fulton et al. (US 2004/0204660). Fulton et al. in claims 1-13 disclose a target tissue location device and method for marking a biopsy cavity comprising all of the limitations of claims 61-71 and 73-76 of the instant application. Regarding claim 72, see Para. 0031 of Fulton et al.

The effective U.S. filing date of Fulton et al. is at least Jan. 27, 1999 (the filing date of the latest provisional application) and predates the effective filing date of the instant application. Although applicant asserts that the provisional applications purportedly do not support the claims of Fulton et al., applicant has provided no

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evidence or analysis whatsoever to support this assertion. It is well settled that mere lawyer's arguments and conclusory statements, which are unsupported by factual evidence, are entitled to little probative value. In re Geisler, 116 F.3d 1465, 1470, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984); In re Wood, 582 F.2d 638, 642, 199 USPQ 137, 140 (CCPA 1978); In re Lindner, 457 F.2d 506, 508-09, 173 USPQ 356, 358 (CCPA 1972).

Reasons for Allowance

The following is an examiner's statement of reasons for allowance regarding claims 31-60:

The examiner is convinced that the prior art of record does not teach nor suggest all of the claimed structure and method limitations including, *inter alia*, a delivery cannula with a ramp inclined to a distal portion of the elongated discharge port such that slidably-disposed marker bodies are urged out of the discharge port by a plunger. The closest prior art, US Pat. 6,220,248 to Vogele et al.. ("Vogele"), discloses a plunger with an inclined surface that assists in urging marker bodies from the cannula outlet as shown in Figs. 6, 7, 9, 11, and 21-25. However, no teaching or suggestion exists to provide an inclined surface on the cannula to assist in dispensing the markers as claimed. The examiner believes that no reasonable suggestion or motivation exists to the skilled artisan to reverse the location of the inclined surface (i.e., from the plunger as shown by Vogele to the cannula as claimed) apart from using applicant's own

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disclosure. To do otherwise would result in using impermissible hindsight reconstruction of applicant's claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John A. Jeffery whose telephone number is (571) 272-4781. The examiner can normally be reached on Monday - Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans, can be reached on (571) 272-4777. All faxes should be sent to the centralized fax number at (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN A. JEFFERY
PRIMARY EXAMINER

5/9/05